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Tribological Characteristics of a Composite Total-Surface Hip Replacement

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Summary

Continuous-fiber, woven E-glass/epoxy composite femoral shells having the same elastic properties as bone were fabricated. These shells were then coated with filled-epoxy, wear resistant coatings consisting of 1- to 64-micrometer particles of either aluminum oxide plus copper (Al_2O_3 + Cu) or 18–8 stainless steel plus aluminum oxide, all components in an epoxy matrix. The resulting femoral shells were wear tested dry against ultra-high-molecular-weight polyethylene (UHMWPE) acetabular cups up to 250 000 cycles on a total hip simulator. The femoral shell yielding the best results contained particles of 18–8 stainless steel plus Al_2O_3 in an epoxy matrix. Articulating this shell dry with a UHMWPE cup for 250 000 cycles resulted in a friction force that was up to 17 percent lower than that of the current total hip prosthesis, that is, a vitallium ball articulating dry with a UHMWPE cup. In a 250 000-cycle wear test a UHMWPE acetabular cup articulating with a standard vitallium ball yielded a wear rate of 1.3×10^{-16} m^3/N-m; the rate for an (18–8 stainless steel + Al_2O_3)/epoxy shell was 3.5×10^{-15} m^3/N-m. Adding graphite fibers to the UHMWPE acetabular cup and articulating with the (18–8 stainless steel + Al_2O_3)/epoxy shell increased the friction force but reduced the surface damage to the UHMWPE. When femoral shells containing Al_2O_3 + Cu particles in an epoxy matrix were run dry against UHMWPE for 42 000 cycles, the friction force continually increased and there was evidence of more surface damage to the UHMWPE cup than for the shell containing particles of 18–8 stainless steel + Al_2O_3.

Introduction

Most current artificial hip joints are composed of a metal femoral stem articulating with an ultra-high-molecular-weight polyethylene (UHMWPE) acetabular cup. Both components are secured with acrylic bone cement. Problems of this design related to bone resorption, acrylic bone cement failure, and loosening or fatigue of the metal stems (refs. 1 to 4) have led to interest in cup or shell arthroplasty. This involves removing of bone from the femoral head and acetabulum and replacing it with matching cups or shells (refs. 5 and 6). However, using metal parts in this procedure may still lead to problems because of the mismatch in elastic properties between metal and bone. This problem has been solved by the analytical design of a continuous-fiber, epoxy composite femoral shell (ref. 7). The composite shell was designed to have the same elastic properties as bone, to have adequate strength, and to be thin enough to require a minimum amount of bone resection. This design raises new questions related to the poor thermal conductivity, high coefficient of thermal expansion, low softening temperature, and creep and wear of the epoxy composite. One possible solution would be to apply a relatively thin coating of a resin impregnated with particles that would make the surface harder and more wear resistant as well as change the thermal characteristics. The tribological characteristics of several filled-epoxy, wear resistant coatings sliding against UHMWPE in bench tests were found to be equivalent to that of 316 stainless steel sliding against UHMWPE (ref. 8).

Therefore the objectives of this investigation were to fabricate continuous-fiber, epoxy composite femoral shells having similar elastic properties as bone, to apply appropriate wear resistant coatings, and to run wear tests of these shells articulating dry with UHMWPE acetabular cups in a total hip simulator. Results were compared with those for a standard vitallium ball articulating with a UHMWPE cup.

The test specimens were fabricated at Rensselaer Polytechnic Institute, and the tests were conducted at the Lewis Research Center.

Methods and Materials

Fabrication of Epoxy/E-Glass Femoral Shells

The results of the analytical composite design (ref. 7) showed that it would take 10 to 12 layers of 0°/90° woven E-glass fibers to make a 2-millimeter-thick epoxy composite shell. A metal shell of this thickness was found to require a minimum amount of bone resectioning (ref. 6). The epoxy/E-glass composite shell would have a safety factor of 2.5 based on a tensor failure criterion when designed as an elastic spherical ball loaded against an elastic semi-infinite body. Thirty percent by volume of E-glass fibers and 70 percent by volume of epoxy would be required to give the shells similar elastic properties as bone.

The epoxy used consisted of a thermosetting resin, Araldite 6010,[1] and an aromatic diamine hardner, XU 205.[1] The epoxy was formed by mixing 100 parts to 32 parts by weight, respectively, of resin to hardener. The continuous-fiber composite shells were formed by laying up a 0°/90° woven E-glass[2] fabric (30 percent fibers by volume), layer by layer, on top of a 43.9-millimeter-diameter spherical die. Flats were machined on two sides of the die to prevent rotation of the shells while they were being wear tested. Once the desired number of epoxy-

[1]Ciba-Geigy, Inc., Ardsley, N.Y.

[2]Woven fabric style 1659, Burlington Glass Fabrics, Altavista, Va.

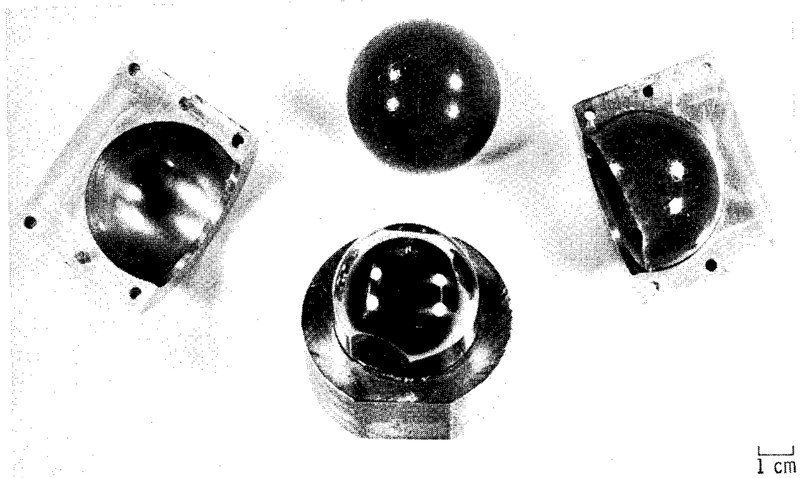


Figure 1. - Two-piece male/female dies for fabrication of femoral shells (also shown).

coated E-glass layers was obtained, a two-piece female femoral mold, with an internal sphere cut in it, was clamped over the composite (fig. 1). This two-piece die butted up against a large nut threaded on the other end of the male femoral die. The nut served to preset the 2-millimeter distance between the male and female dies. The entire apparatus was then set in a pressure chamber in an oven, and a nitrogen pressure of 1.02 MPa (150 psi) was applied to prevent void formation. The composite was gelled for 2 hours at 80° C (175° F) and then cured for 4 hours at 150° C (300° F). The female femoral mold was removed, and the outside radius of the epoxy composite was reduced by 0.200 to 0.254 millimeter (0.008 to 0.010 in.) on a lathe. The outer surface was then coated with wear resistant coatings consisting of particles of either Al_2O_3 + Cu or 18-8 stainless steel + Al_2O_3, all components in an epoxy matrix. The female femoral mold was then repositioned on the shell and the entire apparatus set back in the oven. The coatings were cured in the same manner as the epoxy/E-glass shells. The final continuous-fiber, particulate composite femoral shells were polished in the following sequence: wet 600-grit silicon carbide paper and 1-, 0.3-, and 0.05-micrometer alpha-alumina polishing compound.

Fabrication of UHMWPE Acetabular Cups

The UHMWPE acetabular cups were compression molded in a two-piece male/female die, as shown in figure 2. Two thermocouples, one in the male die and one in the female die, were used to monitor the compression molding temperature. The molding cycle is given in the appendix. Hercules 1900 UHMWPE polymer with and without graphite fibers was used. Five plain UHMWPE acetabular cups and one with 1:20 parts by weight of graphite fibers were molded.

Apparatus

The total hip simulator (fig. 3) was designed to accept various designs of full-size total hip prostheses or a ball-and-socket test specimen and to simulate the motions (ref. 9) and the variable loads (refs. 9 to 11) encountered in the hip joint.

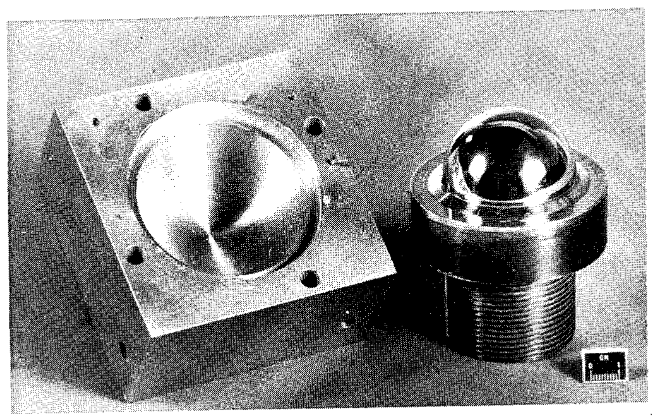


Figure 2. - Two-piece male/female die for molding the ultrahigh-molecular-weight polyethylene (UHMWPE) acetabular cups.

The femoral specimens were mounted in a fixture (fig. 4) extending from the end of an oscillating shaft (fig. 5). The shaft oscillates up to ±18° and simulates the major extension and flexion of the hip joint in the sagittal plane of walking (ref. 9). The shaft was driven by a variable-speed, direct-current electric motor and worm gearbox in unidirectional rotation. An eccentric crank that was adjustable to give the desired extension and flexion was mounted on the output shaft of the gearbox. An adjustable-length crank arm that allows positioning of the ball in the sagittal plane was connected on one end to the gearbox eccentric crank. The other end of the crank arm was connected to a larger eccentric cam on the simulator drive shaft to drive the main shaft in oscillating motion. The femoral specimen was mounted on a bearing assembly in the femoral ball fixture (fig. 4) perpendicular to the drive shaft. The inner bearing assembly holds the femoral ball. It has an arm extending radially from its center. The radial arm is restrained at the extended end and thus, as the drive shaft oscillates, the femoral

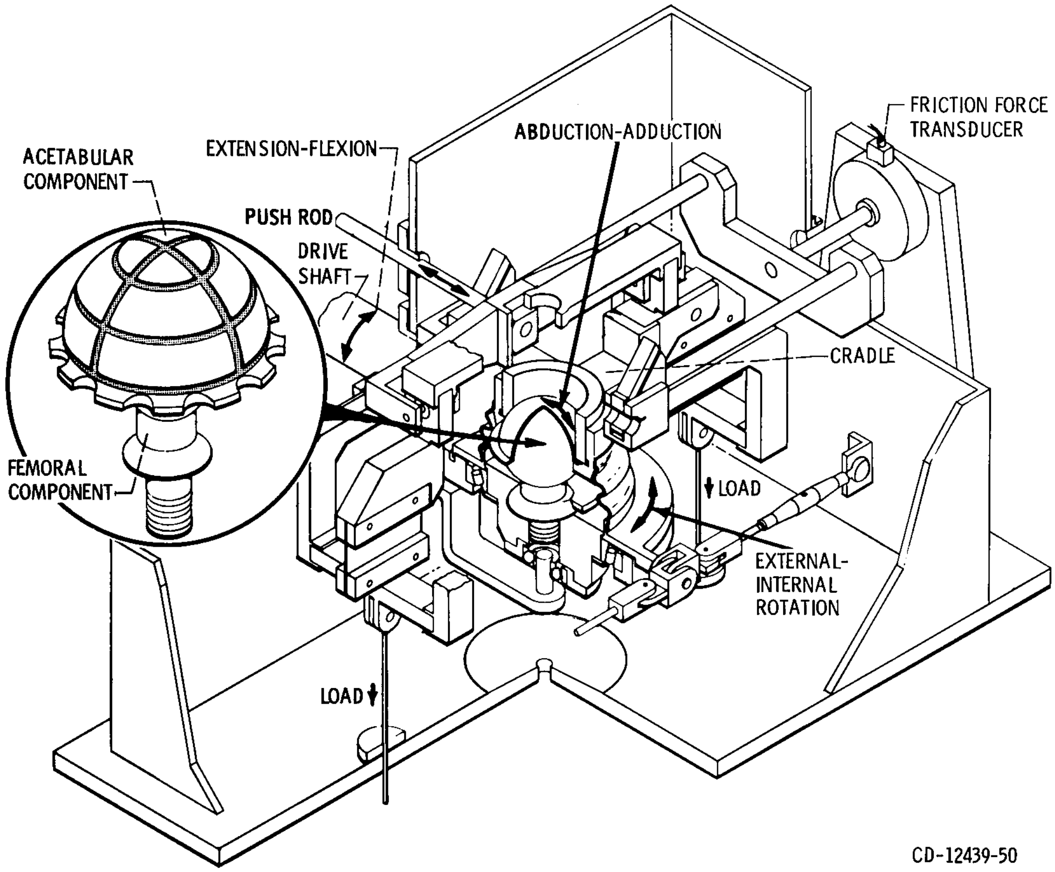


Figure 3. - Perspective and partial cutaway view of total hip simulator with prosthesis specimens, showing direction of motion and load.

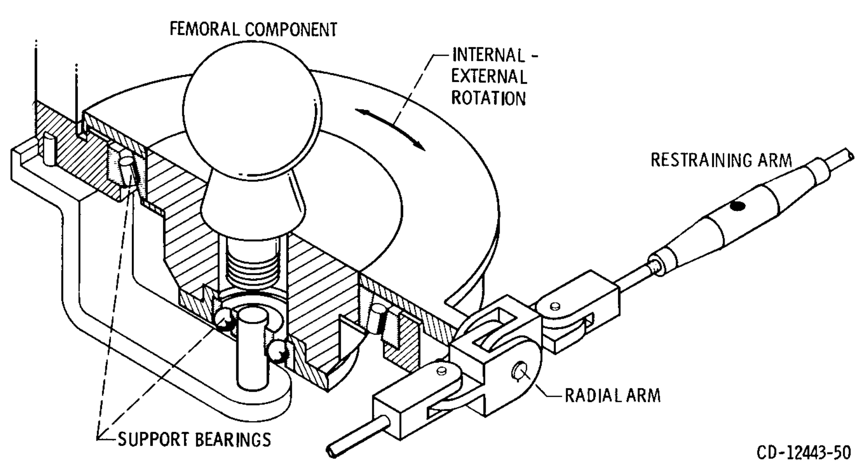


Figure 4. - Test fixture for femoral specimen.

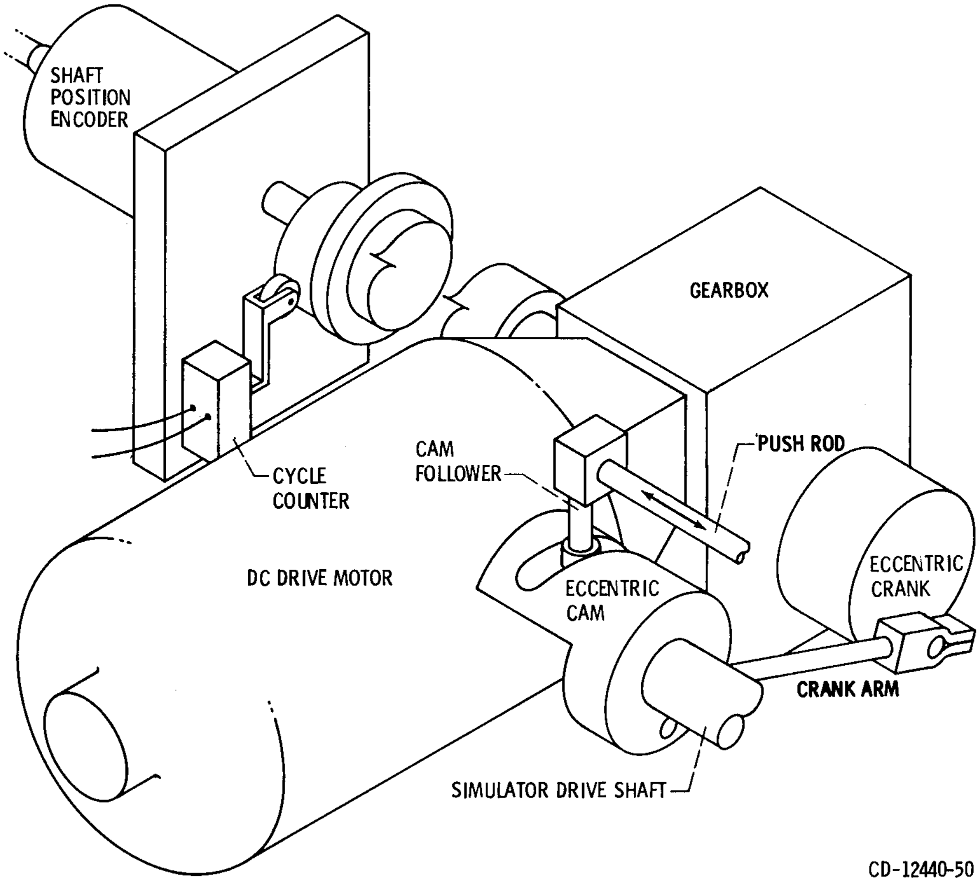


Figure 5. - Total hip simulator drive system.

specimen will oscillate in the transverse plane. For normal walking this oscillation is ±7° (ref. 9). The amount of internal and external rotation is determined by the location of the restraining arm on the radial arm.

The acetabular cup was mounted in a fixture that was stabilized with flexures. These flexures carry the load applied to the prosthesis assembly and permit the acetabular cup to move in a third motion, ±6° (ref. 9), and thus simulate the abduction and adduction motion of walking as encountered in the frontal plane. That simulated motion was on a plane through the main drive shaft centerline. The motion was transmitted with a push rod driven by a cam on the main drive shaft (fig. 5). The cam was designed for the desired motion of the acetabular cup. The acetabular cup fixture has a special flexure suspension and force transducer that enables measurement of the friction force in the sagittal plane.

The load was applied by means of a hydraulic cylinder and a hydraulic pump system through rods and main flexures. The hydraulic cylinder was controlled by a hydraulic servosystem and an electronic programmer. A strain-gage load cell with two strain-gage bridges was connected mechanically to the hydraulic cylinder. One of the bridge circuits served as an electrical feedback to the hydraulic servovalve and the servocontroller amplifier. The second strain-gage bridge was used to measure the load. The output of the load strain-gage bridge was recorded on an oscillographic recorder.

Procedure

The male die on which the femoral shells were formed was modified to fit the femoral ball fixture. The femoral shells and acetabular cups were then assembled (fig. 6) on the femoral ball fixture. The tests were run dry at room temperature (25° C; 77° F) to produce a worse-case wear situation. The standard test was then run at a gait of 30 walking cycles per minute (60 steps/min) and under a programmed load that simulated walking. The loads ranged from 267 to 2940 N (60 to 660 lb), and the load pattern was as shown in figure 7 for a single walking cycle. The friction force as a function of walking cycle was recorded at 2-hour intervals. The test was terminated after 42 000 cycles (~24 hr). Then a series of post-cycle friction tests were performed at constant loads ranging from 125 to 2240 N (28 to 504 lb). Post-42 000-cycle wear test weight measurements were made on the acetabular cups.

During each walking cycle the friction force at the ball-socket interface was continuously measured. A saw-toothed curve normally resulted, with one spike

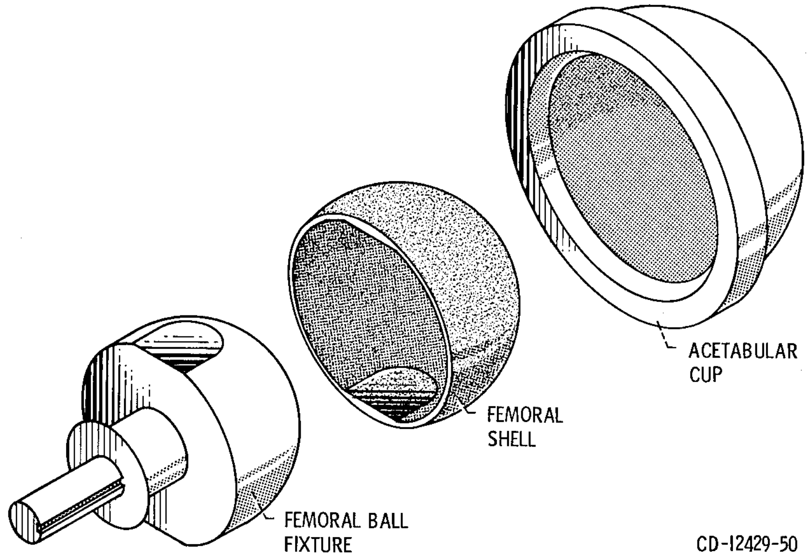


Figure 6. - Femoral ball fixture, femoral shell, and acetabular cup.

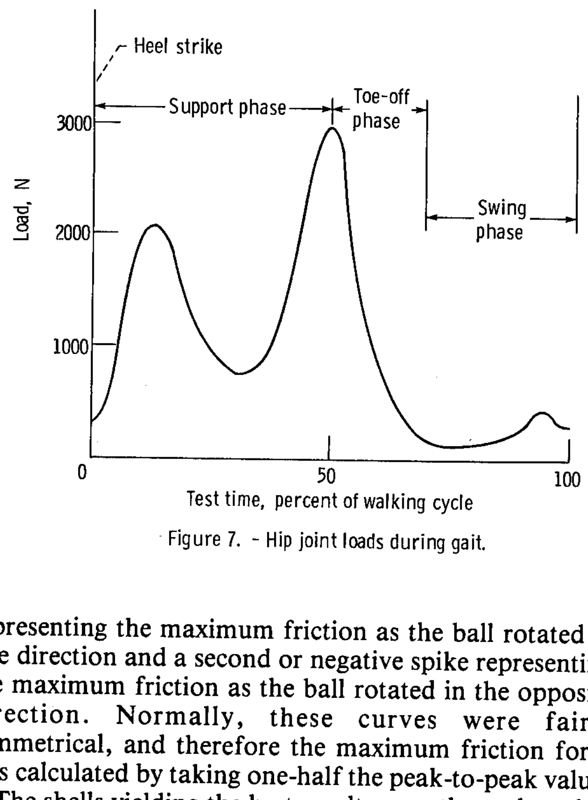


Figure 7. - Hip joint loads during gait.

representing the maximum friction as the ball rotated in one direction and a second or negative spike representing the maximum friction as the ball rotated in the opposite direction. Normally, these curves were fairly symmetrical, and therefore the maximum friction force was calculated by taking one-half the peak-to-peak value.

The shells yielding the best results were then selected to run dry in a 250 000-cycle (~ 1 week) wear test. The same gait and programmed load were used and the friction force was monitored. Pre- and post-test weight measurements were made on the acetabular cups. An optical microscope was used to study the wear surfaces of both the femoral shells and the acetabular cups. Table I shows the test code, the femoral shell code and material, and the acetabular cup code and material.

Results

42 000-Cycle Wear Tests

The results of post-wear-test friction measurements for femoral shells A, B, C, and D articulating dry against acetabular cups E, E, E, and F, respectively, are shown in figure 8. For normal loads ranging from 125 to 2240 N (28 to 504 lb) the friction force after the 42 000-cycle test was lowest in test D/E, that is, the 2:1-parts-weight 18-8 stainless steel/epoxy plus 3:10-parts-by-weight Al_2O_3/epoxy shell articulating with a UHMWPE acetabular cup. The friction force was highest for test B/E, the 1:2-parts-by-weight Al_2O_3/epoxy plus 1:5-parts-by-weight copper/epoxy shell articulating with a UHMWPE acetabular cup. When a vitallium femoral ball (material A) was run with a UHMWPE cup (material E), the friction force was lower than in tests B/E, C/E, or D/F.

Figure 9 shows the maximum friction force as a function of time for all tests during the 42 000-cycle wear test. The friction force stabilized within 10 000 cycles for tests A/E, D/E, and D/F. The friction force during gait was lowest in test D/E, the 2:1 18-8 stainless steel/epoxy + 3:10 Al_2O_3/epoxy shell articulating with a UHMWPE cup. When the vitallium ball (material A) was run against the UHMWPE cup (material E), the friction force had the most stable profile. In tests B/E and C/E, the 1:2 Al_2O_3/epoxy + 1:5 or 2:5 copper/epoxy shells articulating with UHMWPE cups, the friction force continually increased with time. When the copper content was doubled, the friction force (after 4000 cycles) increased about 20 to 30 percent.[3] Adding 1:20 parts by

[3]Throughout this paper all percent changes are calculated as Maximum – Mininum/Maximum × 100.

TABLE I. - TEST CODE, FEMORAL SHELL CODE AND MATERIAL,

AND ACETABULAR CUP CODE AND MATERIAL

Test code	Femoral shell code and material[a]	Acetabular cup code and material[a] (all cups unirradiated)
A/E	(A) Solid vitallium ball (Charnely)[b]	(E) Ultrahigh-molecular weight polyethylene (UHMWPE) (commercial)
B/E	(B) Epoxy/E-glass shell coated with 1:2 Al_2O_3[c]/epoxy + 1:5 Cu[d]/epoxy	(E) UHMWPE
C/E	(C) Epoxy/E-glass shell coated with 1:2 Al_2O_3/epoxy + 2:5 Cu/epoxy	(E) UHMWPE
D/E	(D) Epoxy/E-glass shell coated with 2:1 18-8 stainless steel[e]/epoxy + 3:10 Al_2O_3/epoxy	(E) UHMWPE
D/F	(D) Epoxy/E-glass shell coated with 2:1 18-8 stainless steel/epoxy + 3:10 Al_2O_3/epoxy	(F) 1:20 Graphite fibers[f]/ UHMWPE

[a]All ratios are by weight.
[b]Ball diameter was 22 mm (8.65 in.) as compared with 44 mm (1.73 in.) for composite shells.
[c]1-μm particles, Buehler Ltd., Evanston, Ill.
[d]16-μm particles, Cerac Inc., Menomanee Falls, Wis.
[e]64-μm particles, Metco Inc., Westbury, Long Island, N.Y.
[f]Hercules, Inc., Wilmington, Del.

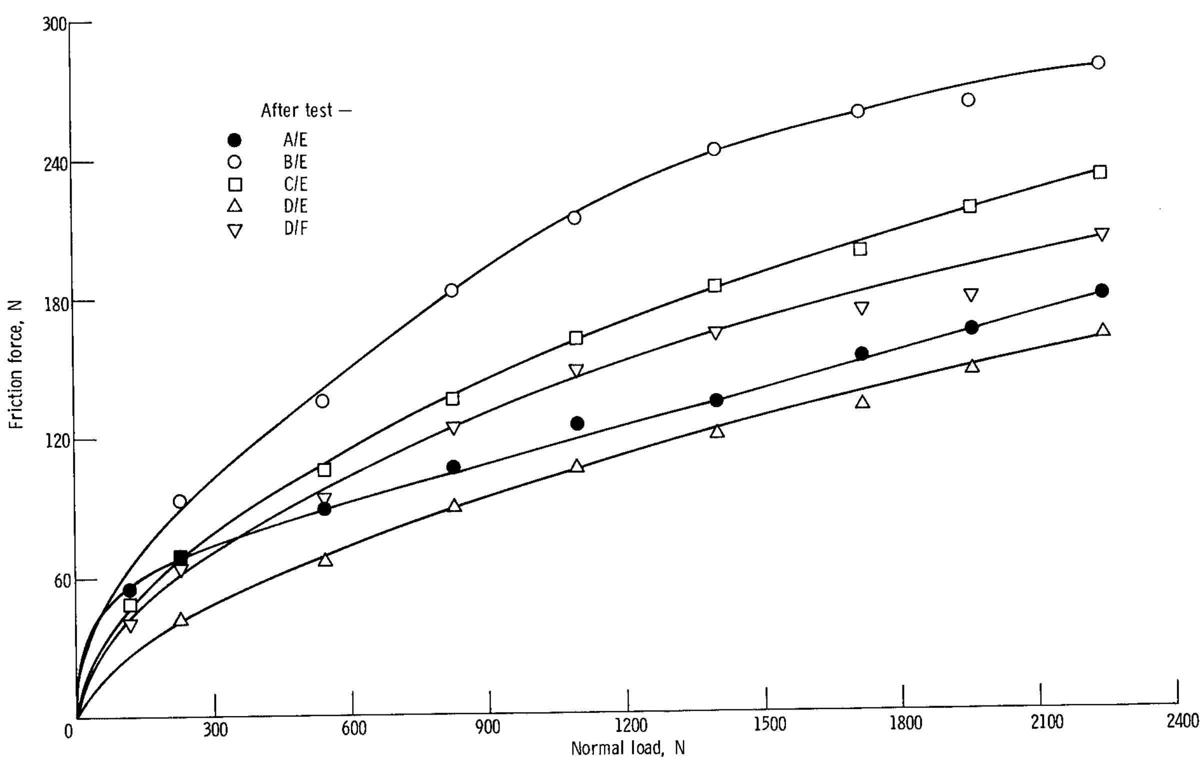


Figure 8. - Friction force as a function of normal load for post-42 000-cycle friction tests.

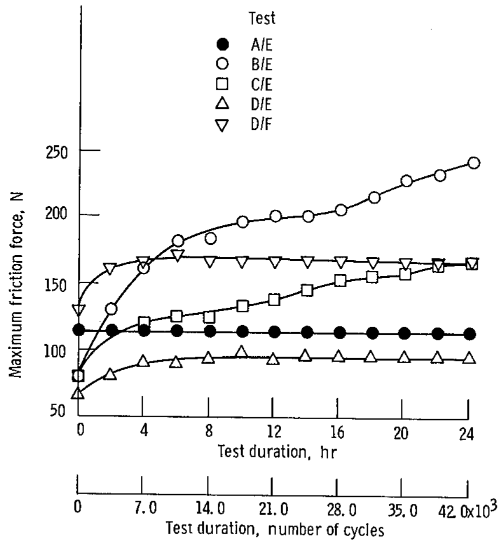
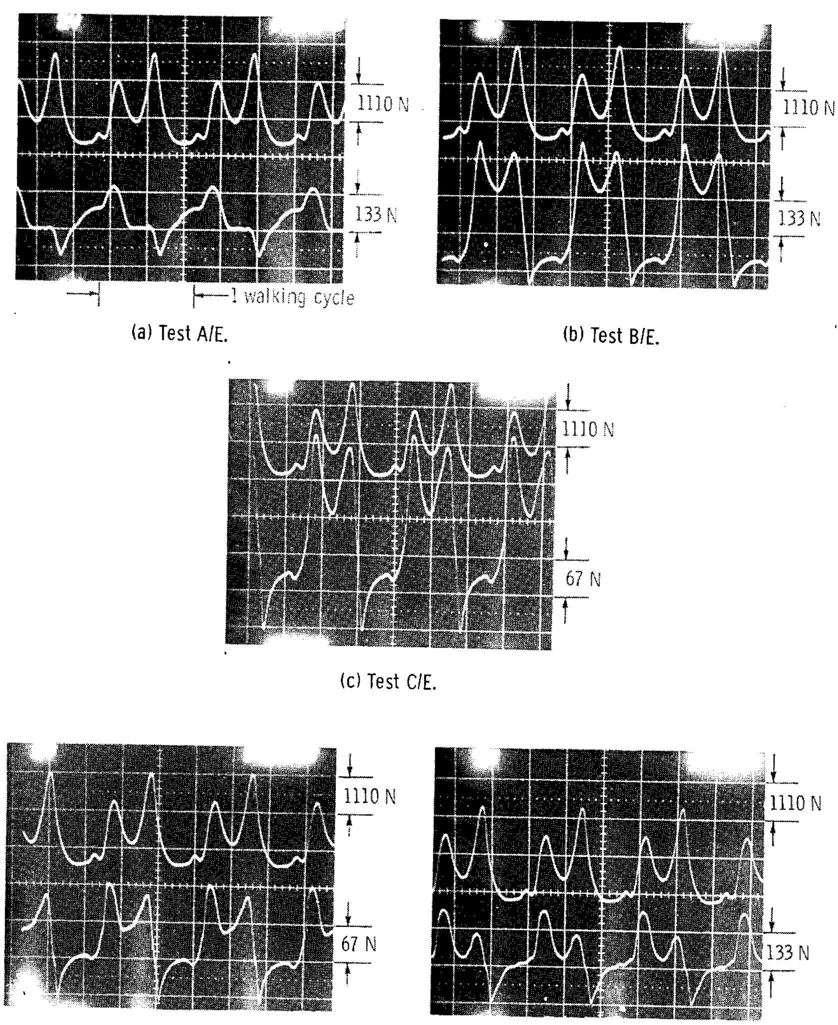


Figure 9. - Maximum friction force as a function of time during 42 000-cycle wear test.

weight of graphite fibers to the UHMWPE (acetabular cup F) and running dry against femoral shell D (the 2:1 18-8 stainless steel/epoxy + 3:10 Al_2O_3/epoxy shell) increased the friction force by about 40 percent as compared with test D/E. During gait the friction force obtained was about 17 percent lower when using femoral shell D than when using material A in articulation against UHMWPE. Figure 10 shows the oscilloscope traces of both the programmed load and the friction force for all tests at the end of the 42 000-cycle wear test.

The acetabular cups from the 42 000-cycle tests were placed in a vacuum chamber and evacuated for a length of time for weight stabilization. They were then weighed in air at intervals prior to testing. This same procedure was followed after testing. The weights were averaged before and after the tests and subtracted to get the weight change. However, the standard deviation of the weight measurements was larger than the weight change for all 42 000-cycle wear tests, thus indicating no measurable wear.



(a) Test A/E.

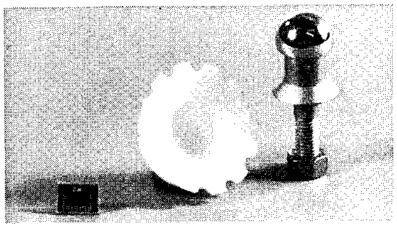
(b) Test B/E.

(c) Test C/E.

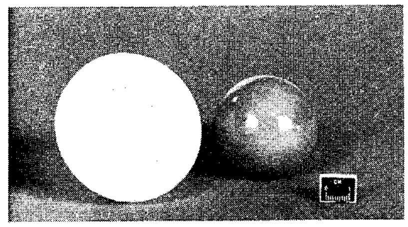
(d) Test D/E.

(e) Test D/F.

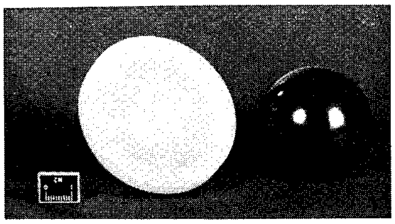
Figure 10. - Oscilloscope traces of programmed load and friction force for tests A/E, B/E, C/E, D/E, and D/F, respectively, at 42 000 cycles (24 hr).



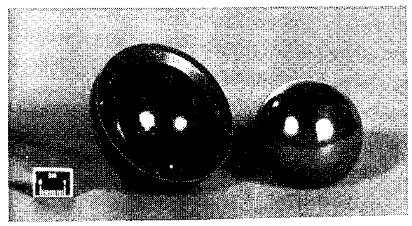
(a) Test A/E.



(b) Test B/E.



(c) Test D/E.



(d) Test D/F.

Figure 11. - Femoral and acetabular specimens after 42 000-cycle wear tests.

Figures 11(a) to (d) show femoral shells and acetabular cups after running for 42 000 cycles for tests A/E, B/E, D/E, and D/F, respectively. Femoral shells B, C, and D (test D/E) were polished in the contact area. There was evidence in shells B and C, the (Al_2O_3 + Cu)/epoxy, of massive UHMWPE transfer and abrasion. The worn area in shells B, C, and D (test D/E) appeared to be in the form of a horseshoe around the polar cap. There was an area about 1.5 centimeters wide directly on the polar cap that was unpolished. The horseshoe extended downward from this about 1.5 centimeters. There was some visual evidence of flakes of abraded UHMWPE on the surface of the vitallium ball (material A). The worn area on shell D, from test D/F, was different from the others in that it extended directly across the polar cap. This area appeared to be covered with graphite, but there was no evidence of abrasion. The UHMWPE acetabular cups from tests B/E and C/E had some discoloration and scratches.

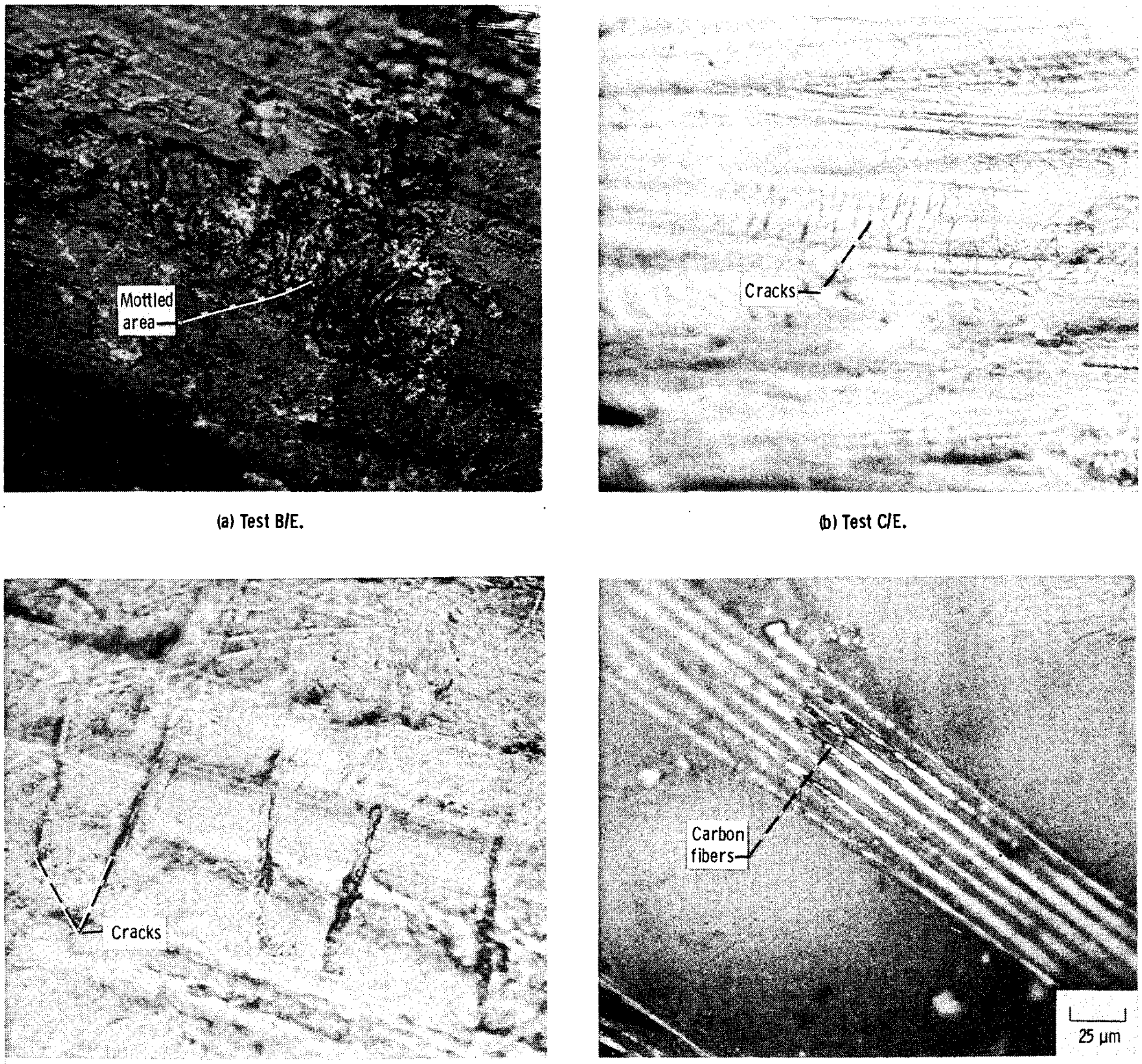
Figures 12(a) to (d) are optical photographs of the polar cap area of acetabular cups from tests B/E, C/E, D/E, and D/F, respectively, after the 42 000-cycle wear test. When femoral shell B was run dry against acetabular cup E, there appeared to be adhesion in the polar cap area (fig. 12(a)). When femoral shell C or D was run dry against material E, the surface damage in the polar cap area appeared to be in the form of small parallel cracks (figs. 12(b) and (c)). The addition of graphite fibers to the UHMWPE increased its resistance to surface damage as can be seen in figure 12(d). Figures 13(a) to (c) are optical photographs in the polar cap area of femoral shells B, C, and D after, respectively, tests B/E, C/E, and D/E. There was little evidence of surface damage in this area to shells B or D. Shell C had some surface scratches.

250 000-Cycle Wear Tests

Femoral specimens A and D were selected for continued testing against acetabular cup material E in 250 000-cycle wear tests. The maximum friction force from 42 000 to 250 000 cycles for test A/E was 121 ± 9 newtons and for test D/E it was 114 ± 2 newtons. There was very little damage to either specimen A (the vitallium ball) or its mating UHMWPE acetabular cup. However, there was evidence of abrasive wear on the UHMWPE cup after articulation against material D (the 2:1 18-8 stainless steel/epoxy + 3:10 Al_2O_3/epoxy shell). There was also evidence of scratches on the surface of shell material D. The weight loss of the UHMWPE cup from test A/E was 0.00044 ± 0.0001 gram. The weight loss of the UHMWPE cup from test D/E was 0.0058 ± 0.0006 gram. The friction and wear results for all tests are summarized in table II.

Discussion

Charnley (ref. 5) theorized that a larger diameter ball would produce higher frictional torques that might loosen the stem or cup. However, according to these results a larger diameter ball may not necessarily produce this effect. For example, test D/E (44-mm-diameter shell) had a friction force 17 percent lower than test A/E (22-mm-diameter ball). Surface roughness, modulus, yield strength, hardness, etc., may also affect the friction force. Materials B and C had friction forces approximately 30 to 40 percent higher at a normal load of 2240 newtons than when shell D was run dry against material E in post-42 000-cycle friction tests. Adding 1:20-parts-by-weight graphite fibers to the UHMWPE (acetabular cup F) and running it dry against shell D increased the friction force approximately 10 to 20 percent between normal loads of 240 to 2240 newtons. Apparently the added graphite increased the plowing component of friction and thus increased the friction force. The friction force was reduced when the copper content was doubled (tests B/E and C/E). This increase in copper content increased the thermal conductivity



(a) Test B/E.

(b) Test C/E.

(c) Test D/E.

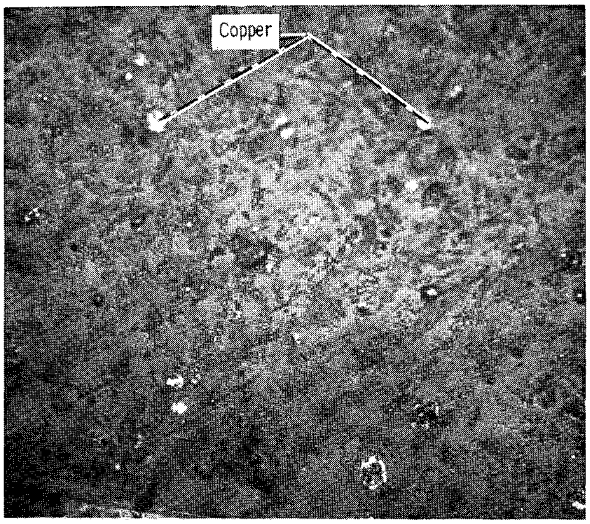
(d) Test D/F.

Figure 12. - Optical photographs of polar areas in ultrahigh-molecular-weight (UHMWPE) after tests B/E, C/E, D/E, and D/F, respectively (42 000-cycle wear tests).

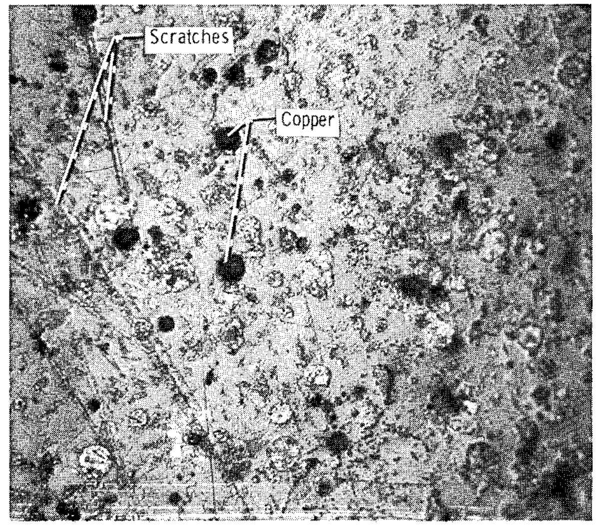
(ref. 8) and helped transfer heat away from the contact area. This in turn may have reduced the adhesive component of friction.

Figure 14 is a plot of the coefficient of friction as a function of normal load for post-42 000-cycle friction tests. The general trend was for the coefficient of friction to decrease with increasing load. The coefficients of friction based on an integrated average load of 1014 newtons during the 42 000-cycle wear tests for A/E, D/E, and D/F were, respectively, 0.11, 0.094, and 0.17. Tests B/E and C/E yielded continuously increasing coefficients of friction throughout the tests. Again, material D articulating with material E had the lowest coefficient of friction.

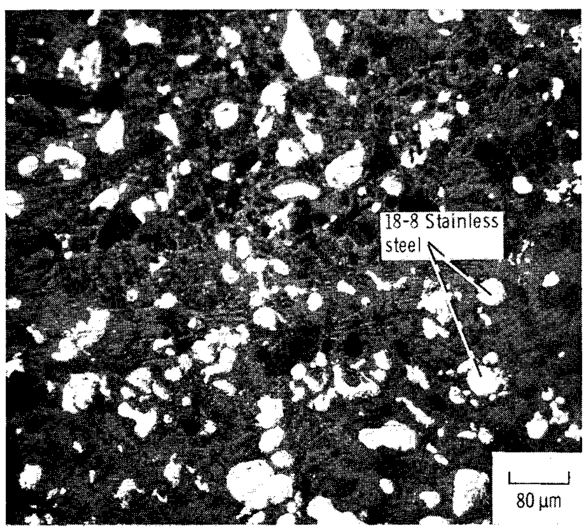
During 42 000-cycle wear tests A/E, D/E, and D/F, the friction force reached a constant value within about the first 10 000 cycles (4 to 6 hr). Apparently the tests (B/E and C/E) involving (Al_2O_3 + Cu)/epoxy could not establish a run-in period. Probably the poor sliding characteristics of copper caused this. At the end of the 42 000-cycle wear test the friction forces for tests A/E and D/E were, respectively, 124 and 97 newtons. During the 250 000-cycle wear test the friction forces for these same two tests were, respectively, 121 ± 9 and 114 ± 2 newtons. This would seem to indicate a very small change in the friction force and hence the coefficient of friction up to 250 000 cycles. However, Amstutz (ref. 12), in a wear study of polymers sliding against SAE 4620 case-



(a) Shell B.



(b) Shell C.



(c) Shell D.

Figure 13. - Optical photographs of polar areas on femoral shells B, C, and D, respectively, after 42 000-cycle wear tests.

hardened steel on an LFW-1 wear test machine, found that the coefficient of friction in mineral oil continually decreased up to 350 000 cycles. In a study of composite-coated epoxy samples running dry against UHMWPE on an LFW-1 wear test machine (ref. 8), it was found that the friction force leveled off after the first 12 hours in a 48-hour wear test. These differences may be attributed to the different test conditions or test apparatus used.

In figure 10 there is a variation in the shape of the friction force traces as a function of the walking cycle for test A/E (fig. 10(a)) as compared with the other tests during the 42 000-cycle wear test. The traces for the vitallium prosthesis in figure 10(a) show one peak at heel strike and one peak at toe-off. However, in all other tests there are three peaks of varying magnitude. It was noticed prior to testing that the fit between the shells and cups was a little too tight. The UHMWPE cups were then put back in the mold and stress relieved by cold compressing. This close fit may have caused the extra friction peak.

Surface Damage

Scratches, gouges, and discoloration were evident in acetabular cups from tests B/E and C/E, and mild scratches and polishing in acetabular cups from tests A/E, D/E, and D/F. The mottled area in acetabular cups from tests B/E and C/E was yellowish-brown in color. This discoloration is probably due to deposits of copper or copper oxides. This may indicate high adhesive forces

TABLE II. - SUMMARY OF RESULTS

Test code	Maximum friction force, N		Coefficient of friction[a] during gait[b]	Wear rate[a] after 250 000 walking cycles, $m^3/N\text{-}m$
	Variable load during gait[b]	Constant-load (2240 N) post-42 000-cycle test		
A/E	114 ([c]121)	178	0.11	1.3×10^{-16}
B/E	Continually increasing: 163 at 4000 cycles 243 at 42 000 cycles	277	0.16 - 0.24	Not run
C/E	Continually increasing: 119 at 4000 cycles 168 at 42 000 cycles	230	0.12 - 0.17	Not run
D/E	93 ([c]114)	161	0.094	3.5×10^{-15}
D/F	168	203	0.17	Not run

[a]Based on integrated average load of 1014 N.
[b]During 42 000-cycle test.
[c]During 250 000-cycle test.

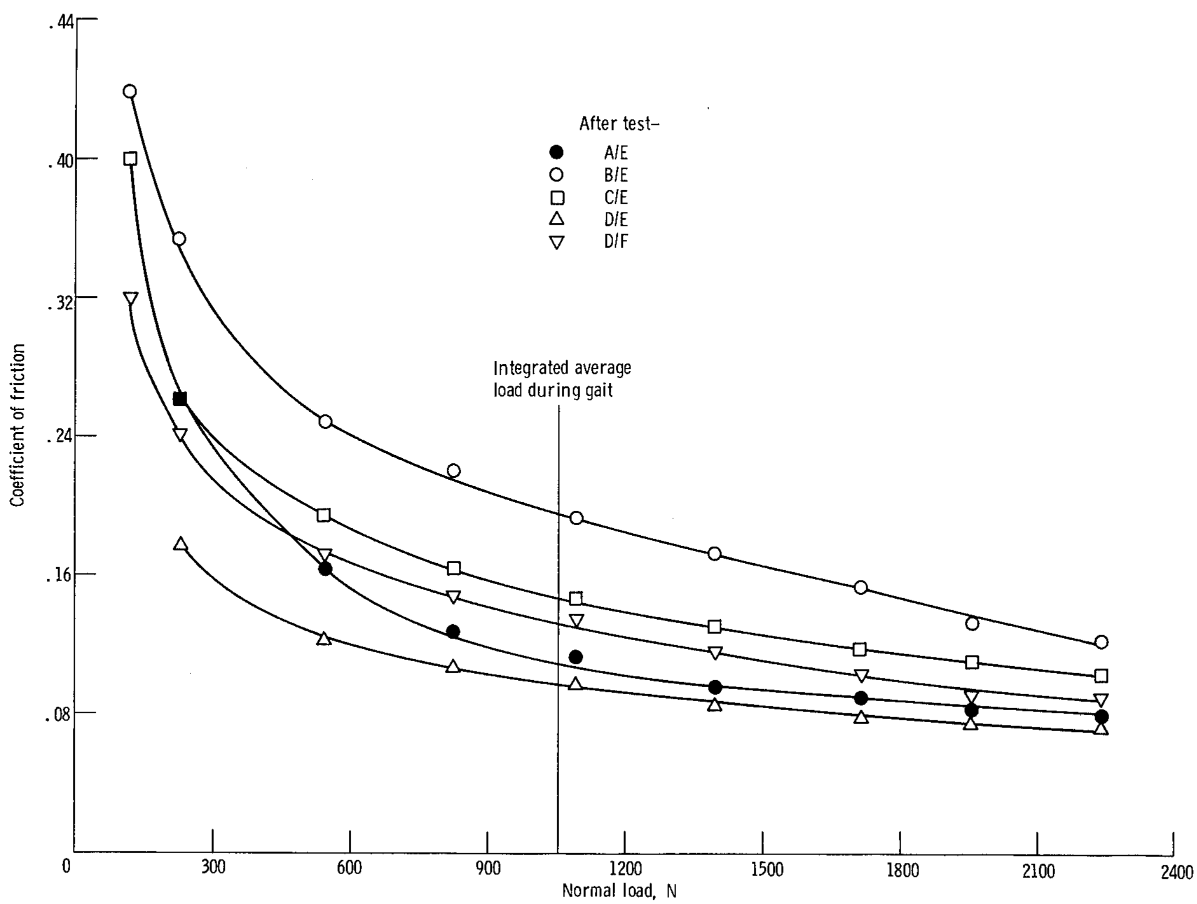


Figure 14. - Coefficient of friction as a function of normal load for post-42 000-cycle friction tests.

removing copper from the shell or poor bonding of the copper to the epoxy. There was evidence of massive transfer of UHMWPE to the surfaces of shells B and C. However, the surfaces of ball A and shell D in tests A/E and D/E were polished with few abrasive scratches. There was ample evidence of graphite transfer to the shell in test D/F in the 42 000-cycle wear test.

The type of surface damage observed under an optical microscope in the polar cap area of UHMWPE acetabular cups from the 42 000-cycle wear test varied from possible adhesion or abrasion to fatigue. Figure 12(a) shows a mottled area that could be the result of an adhesive wear process. This same effect was observed when an LFW-1 wear test machine was used (ref. 8). When the (Al_2O_3 + Cu)/epoxy samples were run dry against UHMWPE for 42 000 cycles, cracks appeared to form perpendicular to the direction of sliding (fig. 12(b)). This same type of surface failure occurred when (18-8 stainless steel + Al_2O_3)/epoxy was used (fig. 12(c)). The wear mechanisms of adhesion, abrasion, and fatigue have been observed by other investigators. Walker et al. (ref. 13) observed abrasive wear and some cracks attributed to microfatigue in the two-piece UHMWPE total surface hip replacement. Rostoker et al. (ref. 14) observed scratches, gouges, and surface cracks in tests done in vitro with a hip joint simulator. Weightman et al. (ref. 15) found cracks perpendicular to the direction of sliding when testing McKee-Farrar or Charnley-Muller prostheses on a total hip simulator. Therefore the types of surface failure observed with conventional prostheses, that is, scratching (abrasion), gouges, adhesion, and cracks were observed for the shells tested here.

Wear

There was some abrasion and polishing of the vitallium ball when run dry against UHMWPE for 250 000 cycles and a cup weight loss of 0.00044 gram. There was evidence of massive abrasion when the (18-8 stainless steel + Al_2O_3)/epoxy shell was run dry against the UHMWPE cup for 250 000 cycles. Powder or flakes of UHMWPE were found in the polar region of the acetabular cup. When these flakes were removed, the resulting weight loss for the UHMWPE cup was 0.0058 gram. Since the UHMWPE has a density of 0.94 g/cm^3 and the sliding distance and integrated average load were, respectively, 1730 meters and 1014 newtons, the wear rate for the acetabular cup in test D/E was 3.5×10^{-15} m^3/N-m. Test A/E yielded a wear rate of 1.3×10^{-16} m^3/N-m. In a study by Brown et al. (ref. 16) the wear rate for UHMWPE sliding dry against surgical-grade stainless steel in a pin-on-disk wear test machine was 1.2×10^{-16} m^3/N-m. Tanaka and Uchiyama (ref. 17) measured the wear of superhigh-molecular-weight polyethylene with a pin-on-disk apparatus. A calculated wear rate of about 5×10^{-16} m^3/N-m was reported. Similar experiments by Jones, et al. (ref. 18) yielded a higher wear rate (1.6×10^{-15} m^3/N-m). Obviously, more tests using a larger sample size and with a simulative joint lubricant would be needed to establish a reproducible wear rate for materials tested in this investigation.

Biocompatibility

The clinical use of any joint prosthesis demands biocompatibility of the materials employed. Some of the materials suggested, that is, UHMWPE, epoxy, and acrylic bone cement, have either been previously used as implant materials or have been shown to be relatively nontoxic in the as-cured or polymerized state when implanted in bulk form as reported by Lee and Neville (ref. 19), Hine et al. (ref. 20), and Escalas et al. (ref. 21). Toxicity of the fibers would be of less importance, to a certain extent, because of their encapsulation and subsequent isolation from tissue. However, in the event that a fiber would extrude into surrounding tissue, its tolerance should be examined. Quartz, a constituent of E-glass, was found to be well tolerated when implanted as a solid block subcutaneously (ref. 22). Aluminum oxide was found to be relatively biocompatible by Salzer et al. (ref. 23). An aluminum oxide endoprothesis was well tolerated in 12 tumor patients. Griss et al. (ref. 24) found Al_2O_3 composites biologically acceptable; however, Escalas et al. (ref. 21) found ceramics to present very poor tissue tolerance. Particles of 316 L stainless steel, which is a commonly used prosthetic material, could be substituted for the 18-8 stainless steel. This might prevent any problems related to the different types of steel as the 316 L stainless steel is now used in total hip prostheses. Copper may be toxic as it is readily absorbed in the blood (ref. 25). When radioactive copper-64 or -67 was administered intravenously to 49 normal subjects, absorption was observed in 30 to 50 percent of the people tested. The toxic effects of copper in intrauterine devices is still under study (refs. 26 to 28). Possibly aluminum could be substituted for copper as its thermal conductivity is about the same as that of copper. At any rate, the final joint prosthesis would certainly have to be tested for tissue biocompatibility and checked for compliance with any ASTM Committee F-4 standard for materials.

Summary of Results

Continuous-fiber, woven E-glass/epoxy composite femoral shells having the same elastic properties as bone were fabricated. These shells were then coated with filled-epoxy, wear resistant coatings consisting of 1- to 64-micrometer particles of aluminum oxide plus copper (Al_2O_3 + Cu) and 18-8 stainless steel plus aluminum oxide in an epoxy matrix. The resulting femoral shells were wear tested dry against ultrahigh-molecular-weight polyethylene (UHMWPE) acetabular cups up to 250 000 cycles on a total hip simulator. The major results were as follows:

1. The femoral shell containing particles of 18-8 stainless steel plus Al_2O_3 in an epoxy matrix articulating dry against a UHMWPE cup yielded the lowest friction

force of all shells tested, even lower than that for a standard vitallium ball.

2. In a 250 000-cycle wear test the wear rate of a UHMWPE cup articulating against a standard vitallium ball was 1.3×10^{-16} m^3/N-m; the rate for the 18-8 stainless steel + Al_2O_3 epoxy shell was 3.5×10^{-15} m^3/N-m.

3. Adding graphite fibers to the UHMWPE cup and articulating it against the composite shell (18-8 stainless steel + Al_2O_3) increased the friction force but reduced surface damage to the cup.

4. Femoral shells containing particles of copper and Al_2O_3 in an epoxy matrix articulating against UHMWPE cups yielded a continually increasing friction force and resulted in more cup surface damage than the 18-8 stainless steel + Al_2O_3 shell.

Lewis Research Center
National Aeronautics and Space Administration
Cleveland, Ohio, April 24, 1981

Appendix—Molding Cycle

The compression molding temperature-pressure sequence for UHMWPE cups is as follows:

(1) Preheat molds to 121° C (250° F).

(2) Preheat powder to 121° C (250° F).

(3) Distribute powder evenly in the female mold.

(4) Place the male plunger in, pressurize to 5.2 MPa (750 psi), and hold for 2 minutes.

(5) Reduce pressure to atmospheric.

(6) Repressurize to 6.9 MPa (1000 psi) for 1 minute, then lower to 3.5 MPa (500 psi) and hold.

(7) Raise temperature to 216° ±3° C (420° ±5° F) and maintain pressure at 3.5 MPa (500 psi).

(8) Hold at 216° C (420° F) and 3.5 MPa (500 psi) for 10 minutes.

(9) Turn off heat and cool for about 15 minutes or until temperature reaches 177° to 163° C (350° to 325° F).

(10) Then cool with frozen blocks[4] to 66° C (150° F). (At 149° C (300° F) repressurize to 6.9 MPa (1000 psi).)

(11) Remove caps.

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[4]Aluminum blocks stored at −29° C (−20° F).

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16. Abstract
Continuous-fiber, woven E-glass composite femoral shells having the same elastic properties as bone were fabricated. The shells were then encrusted with filled-epoxy, wear resistant coatings and run dry against ultrahigh-molecular-weight polyethylene acetabular cups in 42 000- and 250 000-cycle wear tests on a total hip simulator. The tribological characteristics of these continuous-fiber, particulate composite femoral shells articulating with ultrahigh-molecular-weight polyethylene acetabular cups were comparable to those of a vitallium ball articulating with an ultrahigh-molecular-weight polyethylene acetabular cup.

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